

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Douglas T. Gjerde et al.

Application No.: 10/620,155

Filed: 7/14/2003

For: Low Dead Volume Extraction Column
Device

Examiner: Lore Janet Ramillano

Art Unit: 1797

Customer Number: 55130

DECLARATION UNDER 37 C.F.R. 1.132

Douglas T. Gjerde declares as follows:

1. I am an inventor of the subject matter of the above-identified patent application.
2. I received my Bachelor of Science degree in Chemistry in 1976 from Minnesota State University. I received my Ph.D. in Analytical Chemistry in 1980 from Iowa State University in Ames, IA. I am a member of the American Chemical Society and the Honor Society of Phi Kappa Phi. I have 35 peer-reviewed scientific journal publications and 55 issued patents – most having to do with DNA and protein analysis and purification. I am the co-author of 5 books and one medical encyclopedia book chapter - all with Wiley-VCH and an additional book chapter. The 4th Ed. of Ion Chromatography is now being published.
3. I am an expert in several different and distinct disciplines including chromatography, solid phase synthetic chemistry, high performance and high pressure liquid chromatography (HPLC) method development, and HPLC column design. Since founding my present company PhyNexus, Inc., I educated myself and became an expert in solid phase extraction, especially pertaining to active proteins and biological entities and pipette tip column design and methods.
4. My expertise with regard to HPLC column design was acquired in graduate school at Iowa State University and the first two companies I founded: Sarasep, Inc. and Transgenomic, Inc. In this work, I designed and introduced into the marketplace more than 20 commercial HPLC columns. The most successful is the DNASep® column for double stranded and single stranded DNA and RNA separation and purification. This column technology was the basis for founding Transgenomic, Inc. Thousands of columns have been sold to several thousand customers who have used this technology for DNA analysis and purification. In the course of this work, I became an expert on frit requirements for HPLC and nucleic acid separations and on the available frit technology.
5. Although I am an expert in HPLC column design, and solid phase extraction column design, it is highly unusual to possess expertise in both fields. Researchers working in the field of solid

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phase extraction pipette tip column design would not read references on liquid chromatography columns and hardware. One skilled in the art of LC or HPLC column hardware and frit design is not, by definition, one that is also skilled in the art of pipette tip extraction column design.

6. The extraction columns of the claimed invention are sold as PhyTip-brand pipette tip columns. They have been on the market since 2004 and are our main product. We worked for over two years to solve numerous technical problems to make the columns function optimally. The fact that we worked for over two years to overcome numerous technical obstacles indicates the invention is not obvious. If the invention were obvious, someone else would have brought it to market.

7. As an example, we first tried conventional frits of polypropylene and glass wool. The polypropylene frits could be configured to seal around the edges and be placed in a pipette tip. The glass wool could be pushed into the tip. These columns had high backpressure when used with a pipette or a syringe. We were uncertain whether the backpressure was due to frits or resin or both. Although we could get liquids to flow through the tips, the flow was slow and difficult to control. These early columns didn't work for their intended purpose; use of the tips to concentrate protein was unsuccessful.

8. The commercial success of PhyTip-brand pipette tip columns is directly derived from the claimed invention. Claim 1 of the instant invention recites an extraction column, comprised of pipette tip having frits less than 350 microns thick. The thin frits are a core feature critical for the low back pressure of the columns, making it possible to operate the columns with a low pressure pump such as a pipettor or a syringe. Other features responsible for the success of the PhyTip-brand pipette tip are recited in the dependent claims and described in the specification.

9. The commercial success of PhyTip-brand pipette tip columns is not due to extensive advertising. PhyNexus is a small company (less than 20 employees), capitalized through private investment. Because of limited capital, sales and marketing resources have been minimal. For the past year, PhyNexus has had only 1 sales person to cover the U.S. and Europe. Currently there is no marketing manager. Despite the lack of resources for sales and marketing, we have been very successful in the marketplace. PhyTip-brand pipette tip sales and market share have increased each year. We have many repeat sales, currently 80%. Increased sales are largely due to word-of-mouth recommendations and poster presentations at scientific meetings. Much of our promotion is actually performed by our customers.

10. We have sold PhyTip-brand pipette tip columns to top-tier pharmaceutical companies in the U.S. and Europe including Roche, Genentech, GlaxoSmithKline, Merck, AstraZeneca (see attached list of current customers). The columns are used in early stage drug screening by companies such as Roche, GlaxoSmithKline and Genentech. Our PhyTip-brand pipette tip columns have been used by Merck to develop the manufacturing conditions for their Human Papillomavirus vaccine¹ and Pacific Biosciences to discover and screen enzymes for low cost and high throughput DNA sequencing. Our customers have produced numerous papers and publications in which PhyTip-brand pipette tip columns were an essential research tool (see

¹ Biotechnology and Applied Biochemistry, Vol. 47 (Part 2), 131-9, June 2007.

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attached list). PhyTip-brand pipette tip columns have made an impact in how research is done in these companies by saving them money and producing information faster.

11. PhyTip-brand pipette columns have received praise from others. For example, Vertex Pharmaceuticals presented a poster at the 10th Annual Meeting of the Baculovirus and Insect Cell Culture meeting comparing PhyTip-brand pipette tip columns with spin columns and magnetic bead-based technology (see attached poster). They concluded that PhyTip-brand pipette tip columns provided the most accurate prediction of yield for scale-up of Baculovirus-mediated cell expression. This study was performed completely independently of PhyNexus.

12. Experts in the field have expressed disbelief that the PhyTip-brand pipette tip columns perform effectively for protein purification. In 2004, PhyNexus, Inc. licensed Ni-NTA resin from Qiagen for use in PhyTip-brand pipette tip columns. However, Qiagen did not want to license the resin for use in a product that didn't work. Before Qiagen granted a license to PhyNexus, they requested proof that the columns functioned effectively. To address their concerns, we provided published patent application WO 2004/007081 (the PCT application corresponding to the instant application) as well as some additional performance data. After reviewing the information, Qiagen's Associate Director of Business Development, Martin Potgeter expressed surprise that the product performed as well as it did. This conversation was documented by Allen Burge of PhyNexus in an email to Christopher Holman dated March 23, 2004.

13. US Patent 6,527,951 to Tuvim ("Tuvim") relates to LC column and hardware design which is fundamentally different from pipette tip extraction column design. Because of the fundamental differences in the structure and function of LC columns versus solid phase extraction pipette tip columns, the hardware used, such as the frits, are very different. Since the column hardware is completely different, a researcher designing a solid phase extraction column would not look to an LC column for component hardware.

14. Tuvim's chromatographic column is a typical HPLC column comprised of an end fitting and screw (Tuvim, figure 2A) adapted to engage Tuvim's filter. None of the references cited by the Examiner teach devices comprised of an end fitting and a screw (reference numbers 51 and 87 in Figure 2A of Tuvim). None of the references teach devices adapted to engage Tuvim's filter. The pipette tip extraction column of the claimed invention is not adapted to engage Tuvim's filter.

15. Any suggestion in Tuvim that thin filters are desirable for LC does not suggest the use of thin frits in extraction columns. Even if the Tuvim frits could somehow be sealed into an extraction column there is nothing stated or suggested by Tuvim that the frits described in his patent would offer the necessary performance for solid phase extraction columns. Nothing is described as to how the frits would be placed or configured into a pipette tip column. Tuvim shows that his frits require a fitting that compresses the edge of the column to require sealing. He does not suggest what kind of fitting would be needed or could be configured to perform in a pipette tip extraction column. He does not describe how the diameter of the frit could be changed or what type of sealing mechanism could be used since no LC end fitting is present.

16. Liquid chromatography (LC) is a discipline very different from solid phase extraction. LC columns are operated in an instrument that contains a pump, injector, detector, data system and

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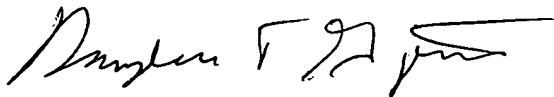
other fitting, tubing and components. The column generates extremely high back pressure and therefore the column, pump and all of the components of the LC system must be designed to operate under high pressure. In the Tuvim patent, the pressure stated to be useful is 10,000 psi, pounds per square inch.

17. The maximum differential pressure that a pipette can apply theoretically is 14 psi, but in practice the standard operating pressure is much lower, usually less than 2 psi. The pipette tip extraction columns of the instant invention can operate even as the pumping force of the pipette or syringe pump approaches zero (as the flow rate through the column approaches zero). Tuvim does not disclose or describe the operating pressures of his frits so there is nothing to suggest that the pressures would be low enough to operate with the pumping limitations of a pipette or a syringe pump used in the invention.

18. Tuvim states that the thinnest available filters are 0.75 micron thick (column 1, lines 42-43). This is certainly a typo because filters of this thickness do not exist and could not exist for LC columns. Tuvim states that UpChurch Scientific, Isolation Technologies, Optimize Technologies, Merck, Alltech and others sell a 0.75 micron thick filter. Filters of this thickness are not available from these companies.

19. As a reference, a sheet of common printer paper has a thickness of approximately 100 microns. A frit having a thickness of 0.75 micron would be 133 times thinner than a sheet of paper. Even with support it is unlikely a frit of 0.75 micron thickness could be manufactured, handled or function to support a bed of LC medium at high pressures. I suspect either the number (0.75) or the unit (micron) was mistyped in the Tuvim patent.

20. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the above-dereference application or any patent issuing thereon.



Date: 6/17/08

Attachments:

- 1) Douglas Gjerde CV
- 2) Current Customer list
- 3) Customer posters and presentations list
- 4) Poster presentation, Vertex Pharmaceuticals

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Education

1976, BS, Minnesota State University, Mankato, MN
1980, Ph.D., Iowa State University, Ames, IA

Summary

Dr. Gjerde has a broad range of business interests including molecular biology, proteomics, polymer bead chemistry, organic chemistry, analytical chemistry and liquid chromatography. Dr. Gjerde's current company, PhyNexus, Inc., is focused on understanding the mechanisms of preparing reproducible and pure protein samples. Through this understanding, superior products for protein manipulation can be produced that integrate seamlessly with different protein analysis technologies that are available on the market.

After serving at research and development positions for several companies, Dr. Gjerde founded Sarasep, Inc. in 1990. Through this company, Dr. Gjerde acquired and developed fundamental DNA separation technology. The technique, called DNA Chromatography, is an advanced liquid chromatographic method for the separation of single strand and double strand DNA. Sarasep developed the DNASep® column, the premier column tool for DNA analysis and purification. Starting from an investment of less than \$2000, the first year sales were approximately \$90,000. Dr. Gjerde built the company to sales of approximately \$2.3M with every year being profitable.

This technology became the basis for a startup company in July, 1997. Transgenomic, Inc. was formed by the merger of 3 companies: Sarasep, Interaction Chromatography (acquired by Sarasep) and Cetac Technologies, an Omaha based instrument company. Dr. Gjerde served as Chief Scientific Officer for Transgenomic where he supervised the company's technical position and guided the development of the first products based on market need. He wrote the prospectus describing the technology and business opportunity and made presentations to help secure pre IPO funding of \$10M and \$12M and then helped achieve a successful \$70M IPO offering in July 2000, three years after the company's founding. DNASep column technology is now being used in several thousand instruments worldwide and is the method of choice for the discovery of genetic mutations with more than 1000 publications describing the technique.

Professional Positions

2002 to present	Founder, Chief Executive Officer, PhyNexus, Inc., San Jose, CA
1997 to 1999	Founder, Chief Scientific Officer, Transgenomic, Inc. San Jose, CA
1990 to 1997	Founder, President, Director of R&D, Sarasep, Inc. Santa Clara, CA
1989 to 1990	Consultant, Saratoga Separations, Saratoga, CA
1984 to 1988	Research Director, Wescan Instruments, Inc., Santa Clara, CA
1981 to 1984	Senior Chemist, Exxon Research and Engineering, Linden, NJ
1980 to 1981	Post Doctorate, Iowa State University, Ames, IA

Awards and Other Professional Activities

1993 to present Reviewer, J of Chromatogr.
1992 to 1995 Reviewer, LC/GC Mag.
1991 to 1995 Scientific Advisory Board, Ion Chromatography Symposium
1979 Phillips Graduate Student Award for outstanding research
1976 Member of the Honor Society of Phi Kappa Phi

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1974 to present Member American Chemical Society

US Patents

1. 7,225,079 System and method for automated matched ion polynucleotide chromatography
2. 7,151,167 Open channel solid phase extraction systems and methods
3. 7,138,518 Liquid chromatographic separation of polynucleotides
4. 7,122,640 Open channel solid phase extraction systems and methods
5. 6,838,242 Modifying double stranded DNA to enhance separations by matched ion polynucleotide chromatography
6. 6,652,745 Column for DNA separation by matched ion polynucleotide chromatography
7. 6,642,374 Process for separation of polynucleotide fragments
8. 6,579,459 System and method for performing polynucleotide separations using liquid chromatography
9. 6,576,133 Method and system for RNA analysis by matched ion polynucleotide chromatography
10. 6,524,480 Non-polar media for polynucleotide separations
11. 6,521,411 Method and system for the preparation of cDNA
12. 6,521,123 Polynucleotide separations on polymeric separation media
13. 6,503,397 Non-polar media for polynucleotide separations
14. 6,491,821 System and method for performing polynucleotide separations using liquid chromatography
15. 6,488,855 Non-polar media for polynucleotide separations
16. 6,485,648 MIPC column cleaning system and process
17. 6,482,317 Polynucleotide separations on polymeric separation media
18. 6,475,388 Method and system for RNA analysis by matched ion polynucleotide chromatography
19. 6,471,866 Process for performing polynucleotide separations
20. 6,461,819 Analysis of nicked DNA by matched ion polynucleotide chromatography under denaturing conditions
21. 6,455,692 Method of concentrating polynucleotides using MIPC
22. 6,419,824 Apparatus and method for separating and purifying polynucleotides
23. 6,372,142 Column for DNA separation by matched ion polynucleotide chromatography
24. 6,372,130 Non-polar media for polynucleotide separations
25. 6,355,791 Polynucleotide separations on polymeric separation media
26. 6,355,417 Band array display of polynucleotide separations
27. 6,355,165 MIPC chromatographic apparatus with improved temperature control
28. 6,342,161 Method for high resolution liquid chromatographic separation of double-stranded DNA
29. 6,309,549 Polynucleotide separations on polymeric separation
30. 6,287,822 Mutation detection method
31. 6,265,168 Apparatus and method for separating and purifying polynucleotides
32. 6,258,264 Non-polar media for polynucleotide separations
33. 6,251,272 System and column for performing polynucleotide separations using liquid chromatography
34. 6,218,153 Target DNA amplification by MIPC and PCR
35. 6,210,885 Modifying double stranded DNA to enhance separations by matched ion polynucleotide chromatography
36. 6,187,539 Analysis of nicked DNA by matched ion polynucleotide chromatography
37. 6,177,559 Process for separation of polynucleotide fragments
38. 6,174,441 Method for performing polynucleotide separations using liquid chromatography
39. 6,156,206 Process for performing polynucleotide separations
40. 6,136,195 MIPC column cleaning system and process
41. 6,103,112 MIPC chromatographic apparatus with improved temperature control
42. 6,066,258 Polynucleotide separations on polymeric separation media
43. 6,056,877 Non-polar media for polynucleotide separations
44. 6,030,527 Apparatus for performing polynucleotide separations using liquid chromatography
45. 6,027,898 Chromatographic method for mutation detection using mutation site specifically acting enzymes and chemicals
46. 6,024,878 Method for high resolution liquid chromatographic separation of polynucleotides
47. 6,017,457 Method for performing polynucleotide separations using liquid chromatography
48. 5,997,742 Method for performing polynucleotide separations using liquid chromatography

49. 5,986,085 Matched ion polynucleotide chromatography (MIPC) process for separation of polynucleotide fragments
50. 5,972,222 Process for performing polynucleotide separations
51. 5,772,889 System and method for performing nucleic acid separations using liquid chromatography
52. 5,393,673 Method for particulate reagent sample treatment
53. 5,338,448 Method of preventing contamination of a chromatography column
54. 5,149,661 Fluid analysis with particulate reagent suspension
55. 4,272,246 Method and apparatus for chromatographic quantitative analysis

Selected US Applications

- 20080090295 Method and device for preparing an analyte for analysis by mass spectrometry
- 20070196833 Open channel solid phase extraction systems and methods
- 20060202922 Method for optimizing a purification procedure
- 20060199945 Solid-phase synthesis in a capillary
- 20060198765 Method and device for sample preparation
- 20060188404 Method and article for sealing a microplate
- 20060124551 Method and device for sample preparation
- 20060118591 Method and device for desalting an analyte
- 20050258097 Method and device for extracting an analyte
- 20050255604 Method and device for extracting an analyte
- 20050130309 Detection of silanol groups on a surface
- 20050045543 Method and device for extracting an analyte
- 20050019951 Method and device for extracting an analyte
- 20050016921 Method and device for extracting an analyte
- 20040224425 Biomolecule open channel solid phase extraction systems and methods
- 20040224329 Three-dimensional solid phase extraction surfaces
- 20040126890 Biomolecule open channel solid phase extraction systems and methods
- 20040072375 Low dead volume extraction column device

European Patents

1. EP1278584B1 MIPC column cleaning process
2. EP1023306B1 System and method for performing polynucleotide separations using liquid chromatography
3. EP0665764B1 Method of preventing contamination of a chromatography column and apparatus for liquid chromatography

Selected European Applications

1. EP1784637A2 Method and device for extracting an analyte
2. EP1702210A2 Method and device for sample preparation
3. EP1521637A1 Low dead volume extraction column devices
4. EP1518115A2 Biomolecule open channel solid phase extraction systems and methods
5. EP1331976A2 System and method for automated matched ion polynucleotide chromatography
6. EP1299166A4 Polynucleotide separations on polymeric separation media
7. EP1299166A1 Polynucleotide separations on polymeric separation media
8. EP1278584A4 MIPC column cleaning system and process
9. EP1278584A1 MIPC column cleaning system and process
10. EP1278583A4 MIPC chromatographic apparatus with improved temperature control
11. EP1278583A1 MIPC chromatographic apparatus with improved temperature control
12. EP1274837A2 Apparatus and method for separating and purifying polynucleotides
13. EP1231993A4 Improved column for DNA separation by matched ion polynucleotide chromatography
14. EP1231993A1 Improved column for DNA separation by matched ion polynucleotide chromatography
15. EP1056528A4 Method for high resolution liquid chromatographic separation of polynucleotides

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16. EP1056528A1 Method for high resolution liquid chromatographic separation of polynucleotides
17. EP1042503A4 Method of detecting mutant DNA by MIPC and PCR
18. EP1042503A1 Method of detecting mutant DNA by MIPC and PCR
19. EP1030933A4 Analysis of nicked DNA by matched ion polynucleotide chromatography
20. EP1030933A1 Analysis of nicked DNA by matched ion polynucleotide chromatography
21. EP1027121A4 Improved liquid chromatographic media for polynucleotide separation
22. EP1027121A1 Improved liquid chromatographic media for polynucleotide separation
23. EP1025113A4 Improved process for performing polynucleotide separations
24. EP1025113A1 Improved process for performing polynucleotide separations
25. EP1023463A4 Modifying double stranded DNA to enhance separations by matched ion polynucleotide chromatography
26. EP1023463A1 Modifying double stranded DNA to enhance separations by matched ion polynucleotide chromatography
27. EP1023306A4 System and method for performing polynucleotide separations using liquid chromatography
28. EP1023306A1 System and method for performing polynucleotide separations using liquid chromatography
29. EP1017841A4 Chromatographic method for mutation detection using mutation site specifically acting enzymes
30. EP1017841A1 Chromatographic method for mutation detection using mutation site specifically acting enzymes
31. EP1017466A4 Polynucleotide separations on nonporous polymer beads
32. EP1017466A1 Polynucleotide separations on nonporous polymer beads
33. EP1002137A4 Denaturing multi ion polynucleotide chromatography for detecting mutations
34. EP1002137A1 Denaturing multi ion polynucleotide chromatography for detecting mutations
35. EP0984978A4 Band array display of polynucleotide separations
36. EP0984978A1 Band array display of polynucleotide separations
37. EP0665764A4 Method of preventing contamination of a chromatography column and apparatus for liquid chromatography.
38. EP0665764A1 Method of preventing contamination of a chromatography column and apparatus for liquid chromatography
39. EP0345782A3 Fluid analysis with particulate reagent suspension
40. EP0345782A2 Fluid analysis with particulate reagent suspension

Journal Articles

1. Rainer M, Muhammad NU, Huck CW, Feuerstein I, Bakry R, Huber LA, Gjerde DT, Zou X, Qian H, Du X, Wei-Gang F, Ke Y, Bonn GK. *Ultra-fast mass fingerprinting by high-affinity capture of peptides and proteins on derivatized poly(glycidyl methacrylate/divinylbenzene) for the analysis of serum and cell lysates*. Rapid Commun Mass Spectrom. 2006; 20(19):2954-60.
2. Bakry R, Gjerde D, Bonn GK. *Derivatized nanoparticle coated capillaries for purification and micro-extraction of proteins and peptides*. J Proteome Res. 2006 Jun; 5(6):1321-31.
3. Hanna C, Gjerde D, Nguyen L, Dickman M, Brown P, Hornby D. *Micro-scale open-tube capillary separations of functional proteins*. Anal Biochem. 2006 Mar 1; 350(1):128-37. Epub 2006 Jan 17.
4. Hecker KH, Taylor PD, Gjerde DT. *Mutation detection by denaturing DNA chromatography using fluorescently labeled polymerase chain reaction products*. Anal Biochem. 1999 Aug 1; 272(2):156-64.
5. Kuklin A, Davis AP, Hecker KH, Gjerde DT, Taylor PD. *A novel technique for rapid automated genotyping of DNA polymorphisms in the mouse*. Mol Cell Probes. 1999 Jun; 13(3):239-42.
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8. Kleindienst, Gerald; Huber, Christian G.; Gjerde, Douglas T.; Yengoyan, Leon; Bonn, Guenther K. *Capillary electrophoresis of peptides and proteins in fused-silica capillaries coated with derivatized polystyrene nanoparticles*. Electrophoresis 1998. 19:262-269.
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13. Gjerde, D. T.; Cox, D. J.; Jandik, P.; Li, J. B. *Determination of analytes at extreme concentration ratios by gradient ion chromatography with solid-phase reaction detection*. J. Chromatogr. 1991. 546:151-8.
14. Jandik, P.; Li, J. B.; Jones, W. R.; Gjerde, D. T. *New method of background eluent conductivity elimination in gradient ion chromatography*. Chromatographia 1990. 30:509-17.
15. Frankenberger, W. T., Jr.; Mehra, H. C.; Gjerde, D. T. *Environmental applications of ion chromatography*. J. Chromatogr. 1990. 504:211-45.
16. Gjerde, Douglas T.; Benson, James V. *Suspension postcolumn reaction detection method for liquid chromatography*. Anal. Chem. 1990. 62:612-15.
17. Nguyen, J. H.; Kim, H. J.; Gjerde, D. T. *Determination of sulfite in foods and beverages*. Am. Lab. (Fairfield, Conn.) 1988. 20:122-6.
18. Gjerde, Douglas T. *Eluent selection for the determination of cations in ion chromatography*. J. Chromatogr. 1988. 439:49-61.
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24. Shultz-Sibbel, G. M. W.; Gjerde, D. T.; Chriswell, C. D.; Fritz, J. S.; Coleman, W. Emile *Analytical investigation of the properties and uses of a new hydrophobic molecular sieve*. Talanta 1982. 29:447-52.
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26. DuVal, D. L.; Fritz, J. S.; Gjerde, D. T. *Indirect determination of cyanide by single-column ion chromatography*. Anal. Chem. 1982. 54:830-2.
27. Gjerde, Douglas T.; Fritz, James S. *Sodium and potassium benzoate and benzoic acid as eluents for ion chromatography*. Anal. Chem. 1981. 53:2324-7.
28. Roberts, K. M.; Gjerde, D. T.; Fritz, J. S. *Single-column ion chromatography for the determination of chloride and sulfate in steam condensate and boiler feed water*. Anal. Chem. 1981. 53:1691-5.
29. Gjerde, D. T. *Ion chromatography with low-capacity resins and low-conductivity eluents*. Report 1980. NUMBER: IS-T-916 PAGES: 171 pp. No. 15851 AVAIL: NTIS.
30. Fritz, James S.; Gjerde, Douglas T.; Becker, Rose M. *Cation chromatography with a conductivity detector*. Anal. Chem. 1980. 52:1519-22.
31. Gjerde, D. T.; Fritz, J. S.; Schmuckler, G. *Anion chromatography with low-conductivity eluents*. J. Chromatogr. 1979. 186:509-19.

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33. Gjerde, D. T.; Schmuckler, G.; Fritz, J. S. *Anion chromatography with low-conductivity eluents II*. J. Chromatogr. 1980. 187:35-45.
34. Gjerde, D. T.; Fritz, J. S. *Effect of capacity on the behavior of anion-exchange resins*. J. Chromatogr. 1979. 176:199-206.
35. Gjerde, D. T.; Wiederin, D. R.; Smith, F. G.; Mattson, B. M. *Metal speciation by means of micro-bore columns with direct-injection nebulization by inductively coupled plasma atomic-emission spectroscopy*. J. Chromatogr., 640:73-78.

Books and Book Chapters

1. James St. Fritz and Douglas T. Gjerde, "Ion Chromatography", 4th Ed, Wiley-VCH, GmbH, Weinheim; New York, 2008.
2. Douglas T. Gjerde, Christopher P. Hanna, David Hornby and Guenther Bonn, "Nucleic Acid Chromatography" in "Encyclopedia of Molecular Cell Biology and Molecular Medicine." Ed. by Robert A. Meyers, Vol. 9, Wiley-VCH, GmbH, Weinheim; New York, 2005.
3. Douglas T. Gjerde, Christopher P. Hanna, and David Hornby "DNA Chromatography", Wiley-VCH, GmbH, Weinheim; New York, 2002.
4. James St. Fritz and Douglas T. Gjerde, "Ion Chromatography", 3rd Ed, Wiley-VCH, GmbH, Weinheim; New York, 2000.
5. D. T. Gjerde and H. C. Mehra, "Ion chromatography speciation of trace metals" in "Trace metal analysis and speciation", Ed by I. S. Krull, Elsevier: Amsterdam; New York, 1991.
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7. James S. Fritz, Douglas T. Gjerde and Christel Pohlandt, "Ion Chromatography" Dr. Alfred Huethig Verlag, GmbH: Heidelberg; New York, 1982, also translated into Russian and Japanese.

Selected Posters

1. Optimization of Protein Separation Using Micro-Scale Separation Columns
2. Automated enhancement and streamlining of therapeutic antibody discovery through the application of micro-scale high-performance protein separation technology
3. Optimization of protein purification using micro-scale separation columns
4. A flexible platform for automated high-performance protein purification using micro scale separation technology
5. Novel strategies for assaying recombinant antibody function with high throughput cell-based assays

PhyNexus, Inc., Current Customer List May 2008

1	Ablynx N.V.	58	Kemp Biotechnologies, Inc.
2	Adimab, Inc.,	59	Lawrence Livermore National Labs
3	Alexion Antibody Technologies	60	Lonza Biologics plc
4	ALZA Corporation	61	Los Alamos National Laboratory
5	Ambrex	62	Max Planck Institut
6	Amgen Inc.	63	Mayo Foundation
7	Applied Molecular Evolution	64	Medical Research Council Technology
8	Arius Research Inc.	65	MedImmune Ltd
9	Astra Zeneca - Waltham. US	66	Merck & Co., Inc.
10	AstraZeneca AB	67	Monsanto
11	AstraZeneca UK Limited	68	MorphoSys AG
12	Biacore AB	69	Nacalai USA
13	BioArctic	70	National Cancer Institute
14	Bio-Connect BV	71	National Research Council Canada
15	Biogen Idec	72	Novartis
16	Biolex Incorporated	73	Novatec Analytical
17	Bioprocessing Technology Institute	74	Novo Nordisk A/S
18	BioSystems International	75	OMEROS
19	Biotechnica	76	Oregon State university
20	BioXtal	77	Oryzon genomics
21	Boehringer Ingelheim - Austria GmbH	78	Pacific Biosciences
22	Brandeis University	79	PerkinElmer
23	Calibrant Biosystems	80	Pfizer, Inc.
24	Cambridge Antibody Technology	81	PSS USA, Inc.
25	Cell Signaling Technology, Inc.	82	Public Health Agency of Canada
26	Centocor R & D	83	RainDance Technologies Inc.
27	Charles River Laboratories	84	Raven Biotechnologies
28	ChemQuest Limited	85	Roche Palo Alto LLC
29	CSL Ltd	86	Sareum Limited
30	Dana-Faber Cancer Institute	87	Scantec Lab AB
31	Diosynth Biotechnology	88	Schering Plough, Inc
32	DNAX	89	Smithkline Beecham Corporation
33	Domantis	90	SOMALOGIC, INC
34	DYAX s.a.	91	Strategic Diagnostics
35	East Coast Bio, Inc.	92	Symphogen
36	EMD Lexigen R&D Center	93	Talecris Biotherapeutics
37	EMD Serono Reprod. Biology Inst. Inc..	94	Target Discovery, Inc.
38	Ensemble Discovery	95	The Institute of Cancer Research
39	EvoGenix Ltd	96	The Wolfson Inst for Biomedical Rsrch
40	Fabrus L.L.C.	97	Thermo Fisher
41	Fisher Scientific	98	Trubion Pharmaceuticals
42	Fisher Scientific AG	99	U.Coll. London Institute of Neurology
43	Fisher Scientific GmbH	100	UCB Celltech
44	FoldRx Pharmaceuticals, Inc.	101	UCLA
45	Foundation for Supporting Medical Edu.	102	University College Dublin
46	Fred Hutchinson Cancer Research	103	University of Ghent
47	Genentech	104	University of Massachusetts Med School
48	Genmab B.V.	105	University of Sheffield
49	GlaxoSmithKline (GSK)	106	University of Vermont
50	GlycoFi, Inc.	107	Vaudaux-Eppendorf AG
51	Harvard University	108	Vertex Pharmaceuticals
52	ICOS	109	VWR INTERNATIONAL
53	Immunogen Inc.	110	Walter Reed Army Inst. Research
54	Inhibitex	111	WATERS CORPORATION
55	Invitrogen	112	Wyeth
56	John Hopkins University	113	ZymoGenetics, Inc.
57	KaloBios Pharmaceuticals, Inc.		

Selected Posters and Presentations

- 1. Space is the Place: Using DOE and Microscale Techniques to Define Process Boundaries.** Marc Wenger, Merck & Co., Inc., West Point, PA USA. Well Characterized Biotechnology Pharmaceutical Symposium, California Separation Science Society. January 27-30, 2008, Washington DC
- 2. Automation of Sample Preparation for CE-SDS-LIF of rMAbs with a Robotic Purification System.** James McElroy, Lynn Gennaro and Oscar Salas-Solano. Late Stage Analytical Development Genentech, Inc, 1 DNA Way, South San Francisco, CA 94080
- 3. Direct Select™ Small Molecule Libraries: A basis to build an efficient lead discovery program.** C. Chiu, K. Franzen, P. Medeiros, C. Kollmann, A. Cooper, R. Baggio, S. Belyanskaya, M. Clark, M. Oliff, J. Franklin, C. Arico-Muendel, S. Hale, B. Morgan, R. Wagner, Praecis Pharmaceuticals, Inc., Waltham, Mass 02451
- 4. Detailed p38-alpha and c-Abl kinase kinetics obtained by a novel, continuous, homogeneous kinase assay and a new affinity methodology.** P. Medeiros¹, R. Baggio¹, C. Chiu¹, S. Hale¹, I. Jensen², M. Gee², H. Sun², L. Lee², K. Low², R. Noble², S. Woo², 2005, ¹Praecis Pharmaceuticals, Inc., ²Applied Biosystems, Inc.
- 5. Automated high-throughput protein purification with PhyTip (PhyNexus) at Micro-scale.** H. Ho, S. Lee, S. Wang, A. Kutach, D. Shaw, M. Ghate, J. Barnett, Roche Palo Alto LLC, Palo Alto, CA 2007.
- 6. Automated sample preparation facilitated by PhyNexus MEA Purification System for oligosaccharide mapping of therapeutic glycoproteins.** B. Prater, K. Anumula, J. Patti, and Jeff T. Hutchins. Inhibitex, Inc., Alpharetta, GA 30009, USA
- 7. Comparison of techniques for small-scale purification of protein.** V. Turner, J.M. Long, P. Wang, N. Dedi, S.B. Renwick, Vertex Pharmaceuticals, Europe
- 8. Affinity-enrichment mass spectrometry with mass defect tags for biomarker validation -CHI proteomic sample preparation.** L. Schneider, Target Discovery, Inc.
- 9. Accelerated antigen identification: a case study.** Raven Biotechnologies, Inc.
- 10. High throughput 96-well purification of biopharmaceuticals for cell-based screening.** M. Jones, D. Pattison, M. Liddament, J. Andrews, R. Franks, C. Russell, S. Clulow, Cambridge Antibody Technology, UK.